PCT/IL 00 / 00320

320

REC'D 10 JUL 2000
WIPO PCT

מדינת ישראל
STATE OF ISRAEL

4

Ministry of Justice
Patent Office

משרד המשפטים
לשכת הפטנטים

This is to certify that annexed hereto is a true copy of the documents as originally deposited with the patent application of which particulars are specified on the first page of the annex.

זאת לתעודה כי רצופים בזה העתקים נכונים של המסמכים שהופקדו לכתחילה עם הבקשה לפטנט לפי הפרטים הרשומים בעמוד הראשון של הנספח.

10/009022

This 08 -06- 2000 היום

רשם הפטנטים
Commissioner of Patents

PRIORITY DOCUMENT
SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

נתאשר
Certified

חוק הפטנטים, התשכ"ז–1967
PATENTS LAW, 5727–1967

בקשה לפטנט
Application for Patent

לשימוש הלשכה
For Office Use

130307	מספר: Number
04-06-1999	תאריך: Date
	הוקדם/נדחה Ante/Post-dated

113/01063

אני, (שם המבקש, מענו – ולגבי גוף מאוגד – מקום התאגדותו)
I (Name and address of applicant, and, in case of body corporate-place of incorporation)

Influence Medical Technologies Ltd.
3 HaSadnaot Street
Herzelia 46728

אינפלואנס מדיקל טכנולוגיס בע"מ
רח' הסדנאות 3
הרצליה 46728

בעל אמצאה מכח הדין LAW ששמה הוא
Owner, by virtue of LAW of an invention, the title of which is

(בעברית) (Hebrew) התקן לתפירת עצם

(באנגלית) (English) **Bone Suturing Device**

hereby apply for a patent to be granted to me in respect thereof.
מבקש בזאת כי ינתן לי עליה פטנט

* בקשת חלוקה – Application of Division	* בקשת פטנט מוסף – Application for Patent Addition	* דרישה דין קדימה Priority Claim		
מבקשת פטנט from Application	* לבקשה/לפטנט to Patent/Appl.	מספר/סימן Number/Mark	תאריך Date	מדינת האגוד Convention Country
No. ____ מס'	No. ____ מס'			
dated ____ מיום	dated ____ מיום			
* יפוי כח: כללי/מיוחד – רצוף בזה / עוד יוגש P.O.A.: general / individual – attached / to be filed later – filed in case ____ הוגש בענין				
המען למסירת הודעות ומסמכים בישראל Address for Service in Israel: פנסטר ושות' עורכי פטנטים בע"מ רח' בזל 16 פ"ת ת.ד 10256 פ"ת 49002				

חתימת המבקש
Signature of Applicant

עבור המבקש
פנסטר ושות'
עורכי פטנטים בע"מ

היום 4 בחודש יוני שנת 1999
This 4 of יוני of the year 1999

לשימוש הלשכה
For Office Use

113/01063

התקן לתפירת עצם

Bone Suturing Device

אינפלואנס מדיקל טכנולוגיס בע״מ

Influence Medical Technologies Ltd.
c:113/01063

BONE SUTURING DEVICE

FIELD OF THE INVENTION

The present invention relates to forming channels through bones and especially to threading such channels with sutures.

BACKGROUND OF THE INVENTION

Attaching a suture to a bone is a task that is well known in the art of surgery. A common solution is to screw a threaded screw into the bone. However, screwdrivers used to perform this task are often complex and/or expensive. Another solution described for example in US. Patent 5,520,700 to Beyar et al., the disclosure of which is incorporated herein by reference, is to insert a threaded bone anchor into the bone. A disadvantage of both this and the previous techniques is that a hard foreign body is left implanted in the body. In general, it is desirable to leave as small an amount as possible of foreign material in the human bone. Additionally, screws and bone anchors typically cause a considerable amount of trauma to the bone, which trauma is undesirable.

PCT publication WO 97/47246, the disclosure of which is incorporated herein by reference, describes a suture insertion device that purports to form channels in a bone for the suture to be tied through the channel. The needles suggested in this PCT publication for forming a curved channel are either curved or are super-elastic needles that are supposed to curve inside the bone. In general, these needles are inserted into the bone at a perpendicular thereto by pushing them along a suitable bore. An alternative method suggested is drilling using a rotary drill, along a curved path. However, it is noted that drills usually damage a large amount of bone.

Biolectron, inc. provides a device ("CurvTek") which drills along a curved path in a bone, from two ends of the path, using air-pressure powered rotary drill bits.

SUMMARY OF THE INVENTION

An object of some preferred embodiments of the invention is to provide a method of fixing a suture to a bone, while requiring a minimum of damage to the bone and/or a minimum of implanted foreign objects, especially hard objects.

An aspect of some preferred embodiments of the invention relates to mounting a bone-boring needle on a rotary hinge. One desirable result is that transfer of power to the head of the needle is more efficient. Another desirable result is a simpler construction. Another desirable result is obtaining a more controllable and/or known path inside the bone. It should be noted that some or all of these desirable results (and others described herein) might not be achieved in some preferred embodiment of the invention.

An aspect of some preferred embodiments of the invention relates to boring a channel through a bone using two opposing needles. One desirable result is that more of the force applied to the needles is utilized to bore into the bone, rather than for pushing the needle away from the bone. In some embodiments, the needles are in a same plane. Preferably, the needles are curved. Alternatively, the needles are straight. In some embodiments, an anvil which does not enter the bone, but which provides a contra-force to the other needle replaces one of the needles.

An aspect of some preferred embodiments of the invention relates to inserting a bone-boring needle into a bone at an angle substantially different from a perpendicular. Preferably, two or more needles are provided, facing each other and applying force to the bone at the same time, in opposite directions and having a main force vector pointed towards a common point.

An additional result of entering the bone at the non-perpendicular angle is that, even in a flat or concave bone, the resulting path is not a full half circle, but only an arc of a circle. In some cases, as described herein, a path which is more than a half circle may be bored. Although an arc path is preferred, in some preferred embodiments of the invention other curves may be formed. Further, although the curves are preferably planar, in some embodiments of the invention, the curves are non-planar, for example being bi-planar (each of two halves of the curve in a different plane).

An aspect of some preferred embodiments of the invention relates to a method of transferring power from a power source to a tip of a bone-boring needle. In a preferred embodiment of the invention, a main leverage point is provided at or about the needle. Optionally, a second leverage point is provided further away from the needle and remote from the power source. In a preferred embodiment of the invention, the power source is a human hand that moves a lever relative to a handle. One desirable result of providing the leverage near the needle is that a less rugged construction is possible. Possibly, the bone-boring device is flexible rather than rigid.

An aspect of some preferred embodiments of the invention relates to a method of threading a bore. In a preferred embodiment of the invention, two needles are inserted from either side of the bore, the needles meet and then one needle is retracted, pulling the other needle and a thread attached thereto along with it. In a preferred embodiment of the invention, the needles form the bore when they are inserted. Alternatively, first the bore is formed and then the needles are inserted.

An aspect of some preferred embodiment of the invention relates to a method of forming a path for a thread in a pair of needles. In a preferred embodiment of the invention,

two needles are inserted into a bore and when the needles meet a path is formed, along and/or through the needles from one side of the bore to the other side thereof. A thread is then threaded through or along this path. In a preferred embodiment of the invention, the needles meet end to end. Alternatively or additionally, the needles meet side to side. One needle may be closer to the bone surface than the other at their meeting point or they both might be the same distance from the bone surface.

An aspect of some preferred embodiments of the invention relates to providing a bone-boring geometry that is not adversely affected by small errors in the placement of a bone-boring head against a bone. In a preferred embodiment of the invention, this invariance is achieved by providing a needle which rotates on a hinge and providing a resting point of said bone boring head near a center of rotation of said needle. Alternatively or additionally, the invariance is achieved by providing a self-leveling bone-boring head that mechanically aligns itself relative to a bony area against which it is placed.

An aspect of some preferred embodiment of the invention relates to a safety mechanism that shelters a sharp tip of a bone boring device, until said tip is to be inserted into a bone. In a preferred embodiment of the invention, the mechanism is controlled from a handle of the device so that the tip is not exposed inadvertently. In a preferred embodiment of the invention, the safety mechanism is a shield that is retracted by applying pressure on the handle of the device. Preferably the applied pressure is the same as that used to activate the device. Alternatively or additionally, the shield is further protected by a safety latch which prevents said pressure from being transferred to said shield unless said latch is in an "armed" state. Alternatively or additionally to a retracting shield, it is the sharp tip which is selectively retracted and advanced, relative to a shield, so that it does not engage tissue unless a desired sequence has been performed.

In a preferred embodiment of the invention, the device is designed to support the following sequence: first the needles are urged towards the bone, so that they compress any soft tissue between them and the bone and then the needles are advanced through the soft tissue (if necessary) to bore a hole through the bone.

An aspect of some preferred embodiments of the invention relates to a safety feature for preventing damage to or from circular needles that are inserted in a bone. In a preferred embodiment of the invention, when a device coupled to said needles is released, the releasing action first retracts the needles and only then allows the device to be moved.

An aspect of some preferred embodiment of the invention relates to sensing and remotely indicating when certain spatial configurations of a bone borer are achieved. In a

preferred embodiment of the invention, when these configurations sensed, a visual and/or audible indication is displayed to a surgeon. Alternatively or additionally, when these configurations are sensed, a function of the borer is locked and/or unlocked. One example of a sensed spatial configuration is an angle of the borer head relative to the bone. Another example is determining if two boring needles meet in the bone in a desired manner.

There is thus provided in accordance with a preferred embodiment of the invention, a bone boring device, comprising:

a hinge;

a handle coupled to said hinge;

at least one curved needle having a tip and rotatably mounted on the hinge, where when said tip is placed against bone and said needle is rotated on said hinge, said needle is urged into said bone. Preferably, said at least one needle comprises at least two needles. Alternatively or additionally, the device comprises a resting point adjacent said hinge, which resting point is adapted to be placed against said bone.

There is also provided in accordance with a preferred embodiment of the invention, a method of boring a path in a bone, comprising:

providing at least one curved needle having an axis;

aiming said needle at said bone, such that said axis is not perpendicular to said bone; and

advancing said needle to bore a hole into said bone. Preferably, boring a hole comprises boring a hole without removing bone tissue. Alternatively or additionally, said at least one needle comprises two needles. Alternatively, said at least one needle comprises only one needle.

There is also provided in accordance with a preferred embodiment of the invention, a bone boring device, comprising:

a needle adapted for boring into bone;

a source of force for advancing said needle, remote from said needle; and

a force amplifier, coupled to said needle and adjacent to said needle.

There is also provided in accordance with a preferred embodiment of the invention, a method of attaching a suture to a bone, comprising:

advancing two needles into said bone to meet inside said bone;

advancing a thread along a common bore defined by said needles after said needles meet; and

retracting said needles.

There is also provided in accordance with a preferred embodiment of the invention, a method of attaching a suture to a bone, comprising:

advancing two needles into said bone to meet inside said bone;

engaging, by one of said needles the other of said needles, which other needle has a thread attached to a portion thereof; and

retracting said one needle, such that at least said portion is carried along by said one needle with said attached thread. Preferably, said portion comprises a tip of said needle. Alternatively, said portion comprises an entire extent of said needle which enters said bone.

There is also provided in accordance with a preferred embodiment of the invention, a bone-boring device, comprising:

at least one curved needle when is operative to extend to bore a hole in a bone;

a base holding said needle and adapted for being placed against a bone

a handle coupled to the base; and

a needle retractor, which retracts said needle when a force on said handle in a particular direction is lower than a predetermined amount and prior to said base retreating from said bone.

There is also provided in accordance with a preferred embodiment of the invention, a bone-boring device, comprising:

at least one curved needle when is operative to extend to bore a hole in a bone;

a base holding said needle and adapted for being placed against a bone

a handle coupled to the base; and

a needle advancer, which advances said needle only when a force on said handle in a particular direction is higher than a predetermined amount and after said force urges base against said bone.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be more clearly understood by reference to the following description of preferred embodiments thereof in conjunction with the figures, wherein identical structures, elements or parts which appear in more than one figure are labeled with the same numeral in all the figures in which they appear, in which:

Figs. 1A and 1B are schematic illustrations of a bone-boring device, in un-activated and an activated configuration, respectively, in accordance with a preferred embodiment of the invention;

Fig. 2 is a schematic illustration of a hinged dual-needle boring-head, in accordance with a preferred embodiment of the invention;

Figs. 3A and 3B illustrate the action of a leveraged hinged dual needle boring head, in accordance with a preferred embodiment of the invention;

Fig. 3C illustrates a replaceable needle-boring head, with needles retracted and with needles extended, in accordance with a preferred embodiment of the invention;

Figs. 4A and 4B schematically illustrate a bone-boring device having a needle extension/retraction mechanism which matches a particular activation logic, in accordance with a preferred embodiment of the invention;

Fig. 5A illustrates a end to end needle configuration, in accordance with a preferred embodiment of the invention;

Fig. 5B illustrates various needle cross-sections for the configuration of Fig. 5A;

Figs. 6A and 6B are a side and a top view, respectively of a side-by-side needle configuration, in accordance with a preferred embodiment of the invention;

Fig. 7A illustrates a top-bottom needle configuration, in accordance with a preferred embodiment of the invention;

Fig. 7B is a cross-sectional view along line B-B in Fig. 7A, showing a detail of the needle configuration;

Figs. 8A-8C illustrate a detachable needle configuration, and its use in boring and threading a bone, in accordance with a preferred embodiment of the invention;

Figs. 8D-8F illustrate a safety latch which releases the detachable needle of Figs. 8A-8C only if the two needles meet, in accordance with a preferred embodiment of the invention;

Figs. 9A and 9B schematically illustrate a hinged single needle boring head, in accordance with a preferred embodiment of the invention;

Fig. 10 illustrates an angle independence of a boring head, in accordance with a preferred embodiment of the invention;

Fig. 11 illustrates a self-aligning boring head, in accordance with a preferred embodiment of the invention;

Figs. 12A and 12B illustrate a thread pusher, in accordance with a preferred embodiment of the invention in an open configuration and in a closed configuration;

Figs. 13A and 13B illustrate a method of passing a thread through the bores of the needles of Figs. 5A and 5B, in accordance with a preferred embodiment of the invention;

Figs. 14A-14D illustrate various stages in a usage of a thread-exchanging needle assembly, in accordance with a preferred embodiment of the invention;

Fig. 15 illustrates a bone-boring head mounted at an end of an endoscope, catheter or trocar, in accordance with a preferred embodiment of the invention;

Fig. 16 illustrates a bone-boring head mounted at a side of an endoscope, catheter or trocar, in accordance with a preferred embodiment of the invention; and

Fig. 17 illustrates a method of treating a fractured bone, in accordance with a preferred embodiment of the invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Figs. 1A and 1B are schematic illustrations of a bone-boring device 100, in un-activated and an activated configuration, respectively, in accordance with a preferred embodiment of the invention. Device 100 generally comprises a base 102 including a bone-boring head 104, a handle 106, possibly including a lever 108 and a shaft 110 interconnecting the handle and the base. In Fig. 1A, a pair or needles 112 of bone-boring head 104 are retracted. In Fig. 1B, when lever 108 is moved towards handle 106, needles 112 extend, boring a hole in adjacent bone.

The device shown is suitable for attaching sutures to an inside face of a pubic bone. Thus, needles 112 extend towards the handle. In use, boring-head 104 is placed against the boring pubic bone, upwards pressure being applied to handle 106 to assure good contact between the boring head and the bone, and then lever 108 is depressed to advance needles 112 and bore the hole. In devices for other uses, bone-boring head 104 may extend away from handle 106.

Fig. 2 is a schematic illustration of a hinged dual-needle boring-head 120, in accordance with a preferred embodiment of the invention. Preferably, head 120 comprises a needle 122 and a needle 124 that share a common hinge 126. When the needles rotate around the hinge, they form a channel 128 in the bone.

In a preferred embodiment of the invention, the needles are arranged to enter the bone at a non-perpendicular angle thereto. Thus, forces applied by the two needles to the bone cooperate to better utilize the forces towards drilling a bore. In the figure, rotation of needle 124 around its hinge applies a force vector FV1, which can be represented by its components FX1 and FY1. Similarly, needle 122 applies a force vector FV2, represented by components FX2 and FY2. An additional force FC is applied by the needles (or by a resting point 134, Fig. 3A below) as a result of a physician urging boring-head 120 against the bone. Force FC is also found in a needle that is directed perpendicular to the bone. FC urges the needle into the bone. However, as the bone has a large resistance to penetration by the needle, a large FC is required to effect that entry, which force is applied from outside the body. In addition, the force

applicator is not stable, allowing the needle to slip and/or penetrate at an undesirable angle and/or form an undesirable channel.

In the embodiment shown, forces FX1 and FX2 are in opposing directions, thus stabilizing head 120 from moving. Also, it is noted that the channel is not perpendicular to the bone surface but also includes a significant X component, already at its start. Thus, once the needles enter the bone, or if the bone is not smooth, the FX forces can start boring in the desired direction immediately. Further, if the FX forces engage the surface, the FY forces can start boring, even without an FC force (or with a reduced one) to hold the needles against the bone, since the bone, overlying the needles, holds them in place. Further, if the needles are forced through soft tissue, once the soft tissue is pierced, the soft tissue assists in holding the needles against the bone.

Additionally, forces FY1 and FY2 are generated at the boring-head, and are least somewhat decoupled from the FY forces, making them easier to control, so that increasing these forces or decreasing them (for example by a sudden give of the bone) do not affect the application of force FC to the handle. Thus, the bone boring is more stable.

Figs. 3A and 3B illustrate the action of a leveraged hinged dual needle boring head 130, in accordance with a preferred embodiment of the invention. in this embodiment, not only are the bone-penetration forces generated near the head, but also any force amplification necessary for generating these forces is also performed near the head, so that less variation in the force needs to be transferred along the device. Thus, a more stable and/or easy to use device is provided.

In head 130, force amplification and transduction is provided by translating substantially linear motion of a lever 136 and a lever 138 into rotation of needles 122 and 124. In a preferred embodiment of the invention, lever 136 and needle 122 are formed of a single piece of material, possibly increasing reliability and/or reducing cost. In a preferred embodiment of the invention, the linear force is applied to lever 136 using an anchor 140, for example a hole. Lever 138 utilizes an anchor 142. A shield 132 preferably prevents the needle tips from engaging tissue when they are retracted. Alternatively (and as shown), the tips of the needles may peek out beyond the shield, but possibly not beyond the resting point 134 (described below).

As can be appreciated from Figs. 2 and 3A-3B, different needle tip force geometries will have different mechanical properties with respect to entering a bone. Different medical situations, bone types, bone surfaces and/or other considerations may require different bore-head configurations. Parameters that may be varied include:

(a) the attack angle of the needles, and especially of the very tip thereof, which can affect the force vectors at the tip (i) when the needle enters the bone and (ii) when the needle travels through the bone; the effect of the attack angle being, for example, neutral, urging the needle towards the hinge, urging the needle away from the hinge or urging the needle in a plane perpendicular to the needle;

(b) penetration depth, i.e., a distance between where the needles meet inside the bone and a resting point 134 of the bore-head against the bone surface (shown slightly separated from the surface, for clarity);

(c) distance between the entry holes;

(d) leverage (affected by the lengths of both the levers and the needles);

(e) cross-section of the needle tip and the needle as a whole (will be described in greater detail below);

(f) threading behavior of the needles (described in greater detail below);

(g) radius of rotation; and

(h) a degree of asymmetry between the parameters of the two needles, for example causing one needle to bore easier than the other.

In a preferred embodiment of the invention, a plurality of replaceable boring-heads is provided, each head having different parameter values. Fig. 3C illustrates a replaceable needle-boring head 150, in accordance with a preferred embodiment of the invention. A plurality of matching protrusions and depressions 154 and 152 are preferably provided on the boring head and on the base of the device, to align the head and the device. In a preferred embodiment of the invention, a coupler 156 and a coupler 158 are provided at the ends of force transmission bars (described in Figs. 4A and 4B) which engage anchors 140 and 142. Preferably the coupler is a snap coupler which can be separated by the application of sufficient force.

Alternatively, the boring head includes means for adjusting one or more of the above parameters. In one example, the penetration depth can be adjusted by increasing a distance between resting point 134 and hinge 126, for example using a screw mechanism. This also affects the distance between the entry holes of the needles.

It should be noted that the two needles may have different cross-sections, different radii of rotation, different leverage, different angles of attack (penetration of the tip) and/or other different features. In some preferred embodiments of the invention, however, the needles are substantially the same. In addition, although the two needles can use different hinges, possibly with a controllable distance (in the X and/or Y axes) between the hinges, in a preferred embodiment of the invention, a single hinge is shared by the two needles.

Figs. 4A and 4B schematically illustrate a bone boring device 200, in accordance with an alternative preferred embodiment of the invention. Device 200 comprises a base 202 having a boring-head such as boring head 130, mounted thereon. Base 202 is connected to a shank 210, having a lever 206 coupled thereto. A contra-force spring 214 couples lever 206 to shank 210. In use, head 130 (actually resting point 134) is placed against a pubic bone (not shown). Lever 206 is pulled away from the boring head against the resistance of spring 214. At this stage, the motion of lever 206 only urges resting point 134 against the pubic bone (the force being transmitted by spring 214), compressing intermediate tissue, but preferably the motion of lever 206 does not extend the needles. After a short travel distance, handle 206 engages an engager, such as a protrusion 216 on a force-transferring element 212. Once engaged, further motion of lever 206 causes force to be transmitted to boring head 130, causing the needles to extend. In a preferred embodiment of the invention, a peg (or other type of latch) 218 further couples lever 206 to force transferring element 212 via an indentation 219 in element 212.

Element 212 rotates one, possibly two levers 220 and 222 around their respective hinges 224 and 226, thereby causing a bar 230 and a bar 232, coupled to the levers, to move along the base and transfer force to the levers of the boring-head (which move as described above with reference to Figs. 3A and 3B). As shown, the levers reduce the transferred force. However, in other preferred embodiments of the invention, the levers increase the transmitted force.

When lever 206 is released, peg 218 forces the needles to be retracted, before reducing the pressure of head 130 against the pubic bone. Thus, there is less likelihood of the needles damaging the bone after the bone boring is completed. In a preferred embodiment of the invention, once the needles are retracted, peg 218 is disengaged (for example by an inclined portion 221 of the peg when it is urged against a protrusion 223) and device 200 can be removed from the pubic bone. Alternatively, peg 218 does not disengage, so that device 200 is substantially a one-use device. Alternatively, peg 218 is disengaged by a specially provided control, such as a button, to prevent inadvertent reuse of the device before the physician is ready for another bone-boring process.

Alternatively or additionally, a safety latch may be provided which does not allow lever 206 to travel far enough along shank 210 to extend the needles, unless the latch is released. Thus, inadvertent damage to tissue by the needles is less likely. Alternatively or additionally, a pin (not shown) may be provided at or about resting point 134, which pin, if depressed with sufficient force, causes the needles or their levers to engage the bars 230 and 232. If an insufficient force is presented, the needles are not coupled to the bars and cannot be

extended. Possibly, a spring is provided at the needles, which spring retracts the needles from the bone if no opposite force is provided by the bars. Thus, if there is insufficient pressure on the pin, the needles are retracted. Such a pin may act in a purely mechanical fashion or may include an electrical circuit to alert the operator and/or actively retract the needles.

It should be noted that a designated resting point 134 is not required. However, in many cases it is desirable that the needles be completely retracted and some element is generally required for compressing intermediate soft tissue and/or for stabilizing the boring head.

In devices not meant for the pubic area, or in devices in which boring head 130 can point away from lever 206, spring 214, protrusion 216 and peg 218 may need to be replaced and/or augmented by suitably located elements which perform their functions.

Element 212 is shown as a bar. However, it is noted that most of the force is applied when extending the needles. Thus, element 212 may have its function served by a wire, preferably with a retraction spring for retracting the needles when lever 206 is released.

Alternatively or additionally, bars 230 and 232 may be replaced by wires. Possibly, a coaxial wire pair is used, in which the inner wire is attached to one lever and the outer one to the other lever. Thus, boring head 130 can be more easily twisted around base 202 and/or otherwise moved.

As can be appreciated, the resistance of spring 214 is related to the total force applied against the pubic bone. In a preferred embodiment of the invention, the tension in spring 214 can be adjusted to require a physician to apply a desirable minimum pressure against the pubic bone. Alternatively or additionally, the linearity of the spring and/or the force constant of the spring may be varied to match a desired profile of applying force to the needles and/or to provide better controllability of the force. In one example, a large force is required to enter the bone, but, once the bone is entered, possibly less additional force is required to continue the boring. In general, it is possible to control the amount of compression force applied to the soft tissue before and after the needles advance, by suitable varying the parameters of the spring, motion of the lever 206 and the force amplification of the power train to the needles.

In some cases it is desirable that the physician "feel" the extension of the needles. This may be achieved by putting a protrusion on shank 210, under spring 214 at a point corresponding to the extension of the needles. Thus, as the lever is pulled a "bump" is felt at that point. Additional such protrusions may be provided at other points on the shank, for example at a point where the needles are fully extended and no further force is required. Alternatively or additionally, to these bumps transmitting feed-back to the physician, the

bumps may be used to control the device, for example as a safety which allows the needles to extend or as a control which "fires" the thread (as described below). Alternatively or additionally, a large protrusion 217 is provided underlying spring 214 and frictionally engaging lever 206, so that compressing the soft tissue will be more difficult than advancing the needles. Possibly, the protrusion applies more friction when the lever is pulled than when the lever is released, for example by suitable machining of its surface. In a typical device the various parameters, such as spring constant, amount of motion and needle leverage are adapted so that 100N force are required to compress the soft tissue prior to the extension of the needles. An additional 40N are required for extension of the needle through a typical pubic bone. The total motion of the lever is 10 mm for compressing the tissue and 4 mm for extending the needles.

Although this embodiment is shown with a single lever 206, a non-movable handle may also be provided, for example for co-gripping with lever 206. Also, instead of manual forces used to power the needle head, air-pressure, electric or other types of power sources may be used.

Once the needles meet, a channel is created in the bone and a thread can be passed through the channel. In a preferred embodiment of the invention, the thread is passed through a channel forming in and/or along the body of the needles. The thread may be inserted with the needles, while they bore, or after the boring is completed. Alternatively, the device is used only to bore a hole in the channel and not to pass a thread, which may be passed manually, for example, if so desired, preferably after the needles are removed.

Fig. 5A illustrates a end to end needle configuration, in accordance with a preferred embodiment of the invention. A needle 240 and a needle 242 meet end to end. It should be appreciated that, in accordance with some preferred embodiments of the invention, better control over the final location of the needles is possible if the needles are rigidly attached to a single hinge than if they do not use hinges or are attached to separate hinges.

Needles 240 and 242 preferably comprise an inner bore, such that when they meet end to end, a path 241 is formed thereby.

Fig. 5B illustrates various suitable cross-sections for needles 240 and 242. Cross-sections 248 and 246 are triangular cross-sections, having a circular inner bore. Cross-section 250 is circular, with a circular inner bore. Cross-section 252 is an example of an open-bore needle, having a "U" shaped cross-section, with the bore on the inside of the "U". Alternatively or additionally, the tip of one needle may be narrow enough to enter the tip of the other needle, forming an inside-outside matching.

Figs. 6A and 6B are a side and a top view of a side-by-side needle configuration, in accordance with a preferred embodiment of the invention. In the embodiment shown in Fig. 6A, a needle 254 and a needle 252 overlap at an area 256 thereof. A bore 258 is formed from the bores of the individual needles. In a preferred embodiment of the invention, the bore of the individual needles do not reach the end of the needle but exit the needle at its side, near the end. When the two needles overlap properly, the bore exits meet and bore 258 is formed.

Fig. 7A illustrates a top-bottom needle configuration, in accordance with a preferred embodiment of the invention. Instead of or in addition to the needles being side-by-side in a plane perpendicular to the needle plane, the needles are one on top of the other (or inside the other, with respect to the view from the hinge), effectively being side-to-side in the plane of the needles. In the embodiment shown, a needle 264 is inside a radius of needle 262, and the two needles overlap at an overlap area 266. Fig. 7B illustrates various possible bores for the overlap area, for example two opposing "U"-shaped bores (268) or two opposing "V" shaped bores (270). This bore may be open for the entire length of the needle or only at the overlap area.

In a preferred embodiment of the invention, the radius of needle 264 is smaller than the radius of needle 262, when measured from the hinge. Alternatively or additionally, the needles are not perfect arcs and/or the radius of the needles does not match the radius of rotation. Properly configured, such construction will cause the needles to engage each other when they meet at overlap 266, instead of sliding over each other. A similar result can be achieved with side-by-side needles, where the needles do not travel in exactly parallel planes, so once they meet, further movement is difficult or impossible.

Figs. 8A-8C illustrate a detachable needle configuration 280, and its use in boring and threading a bone, in accordance with a preferred embodiment of the invention. Configuration 280 includes a non-detachable needle 284, and a detachable needle 282, mounted on a base 286. Needle 284 includes a tip 288 and needle 282 includes a tip 290; these tips are designed to engage, once they meet. Although a particular engagement design is shown, others may be used, for example tip 288 enters into a bore in tip 290 and one or both tips are elastically or plastically deformed so that the tips engage.

As shown in Fig. 8B, once the needles are inserted into the bone, they bore a path and then meet, locking. When the needles are retracted, needle 282 stays latched to needle 284 and is pulled out along the path of needle 284, rather than back along its path. Preferably, a thread 292 is attached to needle 282, such that the thread is pulled along by needle 282 when it advances. Many methods are known in the are for attaching a thread to a needle.

Fig. 8C shows the result of the process, which is a path threaded by a thread 292.

It should be noted that not all of needle 282 needs to be detachable. Rather, it is enough that any part to which the thread is attached is detachable. Thus, in some embodiment, only the tip of needle 282 is detached. Preferably, a groove or a bore is defined in needle 282, so that the boring in the bone does not damage the thread. Also, although needle 284 is portrayed as non-detachable, in some embodiments, it may be desirable to allow needle 284 to be detachable, for example outside the body, for replacement thereof.

In a preferred embodiment of the invention, needle 282 includes a safety latch that releases the needle only if the needle is actually engaged by needle 284, so that needle 282 is not inadvertently left in the bone.

Figs. 8D-8F illustrate a safety latch which releases the detachable needle of Figs. 8A-8C only if the two needles 282 and 284 meet, in accordance with a preferred embodiment of the invention. In the exemplary latch shown, a pin 294 is arranged in a slot 295 in base 286. The base of pin 294 is possibly urged against an incline 296, for example using a spring (not shown). Alternatively to an incline, a flexible pin may be provided which is attached to a fixed location. As needle 282 is advanced, pin 294, urged by the incline, slides in slot 295. At a certain point, the motion of pin 294 releases needle 282. Fig. 8E shown a method in which pin 294 has an aperture 298 formed therein. When the pin is moved, shown in Fig. 8F, the needle is disengaged from the pin and can be extracted by needle 284 that engages it.

Alternatively or additionally, to a mechanical latch, an electrical sensor may be used. This sensor senses when the needles meet, for example from the amount of motion of the needles. Alternatively, the sensor directly senses the contact between the needles, for example by measuring a reduced electrical resistance when the needles meet. The signal generated by this sensor can have one or more uses, including indicating to a physician that contact was made (preferably using a light or a sound), freeing the detachable needle or "firing" a thread (described below).

In a preferred embodiment of the invention, the needles described above are pushed into the bone and they act by forcing a channel through the bone, rather than by removing bone material. Alternatively, in some cases, the needle cross-section may be selected so that the needle removes and/or pulverizes bone, when the needle advances. Preferably, the needle's cross-section, especially at the tip, matches the direction of fibers in the bone, so that it can better enter then bone without cutting across fibers. In a typical implementation, the needles have a radius of curvature of about 6mm, a cross-section diameter of between 1 and 1.5 mm

and are formed of surgical tool grade stainless steel or implant grade stainless steel. However, smaller sizes are possible, for example a radius of 4 or 3mm and a diameter or 0.75 or 0.5 mm.

In a preferred embodiment of the invention, the needles are simply pushed into the bone. Alternatively, the needles may be vibrated (axially, trans-axially and/or rotated), for example using a piezoelectric motor coupled to them, to aid their advancement into the bone.

In a preferred embodiment of the invention, the needles are advanced and retracted by the action of lever 106 or 206, allowing the threading process to be paced by a physician. Alternatively or additionally, the needles may include a self-retracting mechanism, in which, once the needles bore the hole, they are automatically retracted. This may be achieved using a mechanism similar to that of Figs. 8D-8F, which is used to couple the needles to their levers. Preferably, the automatic retraction occurs after the thread is threaded.

In a preferred embodiment of the invention, one of the two needles can be a non-penetrating needle, for example a flat (possibly angled) anvil. Preferably, the anvil includes a hole to receive the other needle. Alternatively or additionally, the anvil also advances when the needle advances. Alternatively, the anvil is fixed. Preferably, the anvil includes small spikes or other gripping elements for engaging the bone so the anvil does not slip and/or to assist in applying a contra-force to stabilize the needle.

Figs. 9A and 9B schematically illustrate a hinged single needle boring head 300, without an anvil, in accordance with a preferred embodiment of the invention. Head 300 comprises a needle 302 connected to a hinge 304 via a needle arm 304. In a preferred embodiment of the invention, needle arm 304 also serves as a needle stop to stop the advance of the needle once it completes its path. Fig. 9B shows the single needle when it complete boring through the bone.

A feature of some preferred embodiments of the invention is an invariance to the angle of incidence between the boring head and the bone. This invariance has several aspects, one or more of which are provided by some preferred embodiments of the invention:

(a) depth of penetration invariance;

(b) slippage invariance; and

(c) bone penetration ability invariance.

Fig. 10 illustrates an angle independence of boring head 130, in accordance with a preferred embodiment of the invention. Due to there being only a small distance between resting point 134 and hinge 126, the penetration depth is unaffected by small, and even some large angles between the resting point and the bone. Since, rotation around the resting point does not substantially affect the distance between the resting point and the meeting point of the

needles. In a preferred embodiment of the invention, the small distance is less than 60%, 40%, 20% or 10% of a radius of curvature of a path along which said needles travel. Due to the simultaneous gripping of the bone by two opposing needles, slippage is prevented. Also, the hinge allows the needles to penetrate the bone at many different attack angles, even if they are not in contact with the bone at a beginning of extension.

Fig. 11 illustrates a self-aligning boring head 320, in accordance with a preferred embodiment of the invention. In this embodiment, head 320 is gimbaled on one or more hinges 326, so that head 320 is always facing to the bone. In a preferred embodiment of the invention, a pair of stabilizers 322 and 324 contact the bone and straighten head 320. Alternatively to an axial hinge, as shown, an integral hinge may be used, for example one formed of silicon rubber. Possibly, three or more stabilizers are provided, to provide stability also in the plane perpendicular to the needle path. Possibly, the tips of the stabilizers are soft, to prevent inadvertent damage to soft tissue. In an alternative preferred embodiment of the invention, head 320 is self-aligning even without such stabilizers, by the unequal forces against the needles causing the head to gimbal.

Alternatively or additionally, to being self-aligning, head 320 can include one or more sensors for determining that the head is in a correct configuration. In one example, a force sensor is provided at each of the stabilizers, to determine a contact force, which should be approximately the same for all the stabilizers. Alternatively or additionally, force sensors are connected to the needles, both of which should measure about equal forces. Possibly, the result of the sensor measurement is portrayed to a user, for example as a go/no-go signal. Alternatively or additionally, the signal from the sensor is used to free a pin, which freeing will allow the extension of the needles. Alternatively, a mechanical construction may be provided, which allows motion of the needles and/or force to be transferred to the needles only if the pressure on the stabilizers and/or their alignment is about the same.

Although the above description of angles has been mainly with respect to an angle in the plane of the needles, similar considerations, measurements and apparatus can be utilized for angles that are between the needle plane and the bone.

Further, the above description has been mainly to needles that share a plane. In some embodiments of the invention, the needles may travel in two oblique planes. An extreme example is cork-screw needles which twist around their own axis (and may be coaxial). Another example is a boring-head comprising three needles, which meet at a point inside the bone.

In various preferred embodiments of the invention, the path bored in the bone can be threaded in different ways. In a first way, a thread is pulled through the path by one of the needles. In another way, the thread is pushed through the path. In yet another way, a separate threaded needle is brought through the path. One the path is threaded, the ends of the suture are tied together, preferably manually. Alternatively, a clip is attached to the two ends of the thread and performs the functions of a knot. In the case where the device performs the threading, when the device is retracted from the one, the thread remains in the bone. The suture may be tied immediately, or in some cases, some or all the required bone bores are formed and threaded and then the sutures are tied.

A general process of bone suturing, in accordance with some preferred embodiments of the invention thus comprises:

(a) compressing soft tissue against the bone;

(b) advancing needles through the soft tissue and the bone, to bore a path through the bone;

(c) advancing a thread along the path, preferably while the needles are still in the hole (or by the advance of the needles);

(d) removing the device (generally first retracting the needles); and

(e) tying the ends of the thread.

In various embodiments of the invention, selected ones of these steps may be performed sequentially or simultaneously. Even in cases when sequential steps are performed, the transition between the steps may be automatic, for example advancing a thread one the needles are fully extended, or manual, for example requiring a user action (manually advancing a thread) or allowance (releasing a safety latch).

As indicated above, a thread may be pushed through the bores of the needles, after they meet. Generally, pushing a thread will require the thread itself to be stiff or to be attached to a stiff thread pusher, which is pushed and carries the ductile thread along with it. The stiffness of the thread/thread pusher depends, inter alia, on the radius of the bore, the amount of bone material in the bore and the type of mechanism used to advance the thread.

Figs. 12A and 12B illustrate a thread pusher 330, in accordance with a preferred embodiment of the invention in an open configuration and in a closed configuration. In a preferred embodiment of the invention, pusher 330 is formed of an elastic or super elastic material and has an eye 332 formed at one end thereof. A thread is threaded through the eye and then the thread pusher is inserted into a channel (or the needle bore). The dimensions of

the channel compress the eye, so that it grips the thread. Alternatively, a double thread may be used, so that both ends of the thread are far away from the eye.

Figs. 13A and 13B illustrate a method of passing a thread through the bores of the needles of Figs. 5A and 5B, in accordance with a preferred embodiment of the invention. A channel 334 contains thread pusher 330. A lever 338 is coupled to thread pusher 330, such that moving the lever advances the thread pusher. Depending on the configuration used, reference number 336 may indicate an extension of thread pusher 330 or a thread attached to thread pusher 330.

In Fig. 13A, the needles meet, but lever 338 maintains the thread outside the needle bore. In Fig. 13B, the lever is depressed and the thread is advanced through the needle bore. Possibly, an engager 340, possibly a friction element engages thread pusher 330, so that it does not retract when the needles are retracted and/or when the device is removed from the bone. In embodiments where the needles retract automatically when the bore is threaded, engager 340 may also release a catch on a spring that retracts the needles.

In one embodiment of the invention, thread pusher 330 is urged forward by a spring 342 (shown schematically). However, advance of pusher 330 is prevented by lever 338. In other embodiments, a pin, such as shown in Figs. 8D-8F, prevents the thread pusher from entering the needle bore, even if it is urged forward by a spring. Preferably, the tip of thread pusher 330 is preloaded into the tip of needle 242, so that it travels with the needle. Alternatively, channel 334 is arranged so that it has a clear view of the bore only when the needle is fully extended.

In some embodiments, bar 232 and/or bar 230, when they completely extend the needles, continue their travel (preferably sliding along anchors 140 and 142) and are used to relapse the thread pusher and/or to advance it.

Figs. 14A-14D illustrate various stages in usage of a thread-exchanging needle assembly 350, in accordance with a preferred embodiment of the invention. Assembly 350 preferably comprises a needle 352, a needle 354, a tip 356 mounted on needle 350 and attached to a thread 358. The tips of needles 352 and 354 are formed to engage tip 356 in the following manner. Tip 356 is preferably frictionally engaged by needle 352 so that it does not fall off (Fig. 14A). When the two needles are brought together, the point of tip 356 is engaged by an inner bore (or other spatial configuration) of needle 354 (Fig. 14B). When the needles are retracted (Fig. 14C), the engagement of the tip by needle 354 is stronger than was the engagement by needle 356, so that the tip travels with needle 354. When the device is removed, thread 358 remains in the bore (Fig. 14D). In some embodiments of the invention,

needle 354 is replaced by an anvil (which does not enter the bone) or by a tip-engager that is distanced from the bone, but is within the needle track.

In all of the above figures, the thread has been shown traveling from a left needle to a right needle. It should be appreciated that this convention, as well as other conventions related to mirroring and relative placement of device elements have been adopted for simplicity of description and should not be construed to limit the preferred embodiments to those shown, for example, a thread may travel from the needle on the side of the shank to the needle on the outside of the device (unlike shown in Fig. 13A).

In a preferred embodiment of the invention, the device or parts thereof are made for one time or limited time used. Thus, sterilization of the device can better be achieved. Further, issues of wear and maintainability are solved, allowing a cheaper device to be manufactured. In one embodiment, the device is a one-patient device and the needles are one-time use. Alternatively or additionally, the needles are one-patient use and the sutures are one-time use. Alternatively, the device is a multi-use device and the boring head is replaceable. In the example of Fig. 12A, the thread and its channel may comprise a disposable cartridge. In the example where lever 338 is not needle or replaced by a latch pin and/or spring 342, a cartridge may comprises a plurality of pre-threaded thread pushers, which are advance one at a time, out of a cartridge (shown as 343 in Fig. 12B) into the needle bore. As one needle pusher is advanced, the next one becomes available for advancing and comes into contact with spring 342. The retraction of the needles preferably cocks spring 342.

In a preferred embodiment of the invention, even in a disposable device, the device is tested, preferably on a piece of test material (possibly an in vitro bone), after it is manufactured or prior to its being used by the physician, to insure that the device is operating properly.

The above description has focused on forming holes in a pubic bone, especially for attaching a thread through the hole for a bladder sling or a bladder or bladder neck suspension. However, a similar device may be used for other applications. In one broad class of uses, the channel is used for attaching soft tissue to a bone, using a thread that grips the bone and is engaged by the channel. Examples of attaching soft tissue include correction a dislocating shoulder (e.g., Bankard procedure), hyoid suspension, and cosmetic applications, such as tightening flabby flesh, by suturing it to a bone.

Fig. 15 illustrates a bone-boring head 360 mounted at an end of an endoscope, catheter or trocar 362, in accordance with a preferred embodiment of the invention. Fig. 16 illustrates bone-boring head 360 mounted at a side of endoscope, catheter or trocar 362, in accordance with a preferred embodiment of the invention. It is expected that only a small pressure is

needed to maintain head 360 against a bone prior to the needles engaging the bone. In a trocar, which is substantially rigid, the pressure may be achieved by pushing against the trocar. IN an endoscope, which is usually somewhat rigid, the pressure may be applied through the endoscope. In flexible endoscopes and/or flexible catheters, the pressure may be applied by advancing the endoscope and using the surrounding body tissues to apply a contra force. In some of these small-diameter devices, levers may not be suitable, due to space constraints, however, other ways of rotating the needle(s) around the hinge may be used, for example, using a screw mechanism. In some cases, a clamp (not shown) may be provided to hold head 360 against the bone, the clamp may engage bone or it may engage nearby soft tissue.

In a preferred embodiment of the invention, an endoscope or trocar is used for cosmetic surgery, when a minimal diameter hole is formed in the body, preferably in a hidden location a boring head 360 is brought to a location where soft tissue is to be attached to bone. The suture is applied, as described herein and the thread is tied through the hole. Thereafter, the hole is sealed. This type of procedure may be especially useful for the face when implantation of staples or screws or long incisions may not be viable options.

Another class of uses is attaching implants, either using a suture, as described above or by inserting a projection of the implant into a channel formed in the bone.

Another class of uses is treating fractures of bones. In one example, small bones, such as wrist bones may be immobilized or prevented form moving apart by threading them together. Preferably, first a channel is formed in each bone and then the bones are sutured to each other (or to soft tissue, such as ligaments) Further, in cases where there are many bone fragments, such as in skull injuries or in cases of shattered jaw bones, the fragments may be stitched together. In some cases it is advantageous for the needles to oppose each other (180 degrees), possibly traveling in straight lines towards each other. Optionally, a large radius of rotation around the hinge approximates such straight lines.

In a preferred embodiment of the invention, bone fragments are attached to a structural element that maintains them in place. Fig. 17 illustrates a plate 374 which is sutured to a fractured bone 370, using a plurality of sutures 372. Optionally, holes are pre-formed in the structural element for receiving the needles. Alternatively, the holes in the structural element may be bored in a single step with boring the holes in the bone. Possibly, a biodegradable structural element is used, so that there is no need to remove it after the bone heals. Another relevant procedure is sternal suturing in which a cut-open rig cage is sutured shut. In a variation of the above embodiment, plate 374 may be an intramedullar nail (possibly not filling the entire cross-section but functioning like plate 374) which is inside the bone.

The above description has focused on boring holes through bones. However, it should be noted that various aspects of the invention may be applied towards other, similar medical applications. In one example, it is noted that self-aligning and the various safety mechanisms are also useful for screw driving devices and for staplers, for example, to prevent slippage, incorrect penetration and/or inadvertent damaging of soft tissue.

With regard to staplers, the above described force transduction mechanism may be used, noting, that unlike needles, the staples remain in the body. Possibly, the staples are inserted side by side with a pair of needles, each of which needles includes a grove for receiving an arm of the staple and which needle does the actual boring. Thus, the staple itself can contain less material and/or otherwise be mechanically weaker.

Additionally, the above device may be used for tacking, which is a method where a suture or other object is attached to a bone by its being pressed between a tack and the bone. A more complete description of tacking can be found in Israel patent application number 127,978 filed January 8, 1999, by applicant Influence Medical Systems Ltd., and titled "Incontinence Device", the disclosure of which is incorporated herein by reference.

Additionally, the above device can be used for implanting a bone anchor, noting that since the hole is bored by a needle, the bone anchor can be made with less material, weaker material and/or from bio-absorbable material.

Additionally, the above-described mechanisms are useful for inserting objects into a bone at a non-perpendicular angle thereto.

It will be appreciated that the above described methods of forming a channel through bone and threading the channel and devices therefore may be varied in many ways, while remaining within the scope of the present invention. In addition, a multiplicity of various features, both of methods and of devices has been described. It should be appreciated that different features may be combined in different ways. In particular, not all the features shown above in a particular embodiment are necessary in every similar preferred embodiment of the invention. Further, combinations of the above features are also considered to be within the scope of some preferred embodiments of the invention. Also within the scope of the invention are surgical kits that include sets of bone-boring devices, bone-boring heads, needles and/or sutures. When used in the following claims, the terms "comprises", "includes", "have " and their conjugates mean, "including but not limited to".

A person skilled in the art will appreciate that the present invention is not limited by what has thus far been described. Rather, the scope of the present invention is limited only by the following claims.

CLAIMS

1. A bone boring device, comprising:

a hinge;

a handle coupled to said hinge;

at least one curved needle having a tip and rotatably mounted on the hinge, wherein when said tip is placed against bone and said needle is rotated on said hinge, said needle is urged into said bone.

2. A device according to claim 1, wherein said at least one needle comprises at least two needles.

3. A device according to claim 1 or claim 2, comprising a resting point adjacent said hinge, which resting point is adapted to be placed against said bone.

4. A method of boring a path in a bone, comprising:

providing at least one curved needle having an axis;

aiming said needle at said bone, such that said axis is not perpendicular to said bone; and

advancing said needle to bore a hole into said bone.

5. A method according to claim 4, wherein boring a hole comprises boring a hole without removing bone tissue.

6. A method according to claim 4 or claim 5, wherein said at least one needle comprises two needles.

7. A method according to claim 4 or claim 5, wherein said at least one needle comprises only one needle.

8. A bone boring device, comprising:

a needle adapted for boring into bone;

a source of force for advancing said needle, remote from said needle; and

a force amplifier, coupled to said needle and adjacent to said needle.

9. A method of attaching a suture to a bone, comprising:

advancing two needles into said bone to meet inside said bone;

advancing a thread along a common bore defined by said needles after said needles meet; and

retracting said needles.

10. A method of attaching a suture to a bone, comprising:

advancing two needles into said bone to meet inside said bone;

engaging, by one of said needles the other of said needles, which other needle has a thread attached to a portion thereof; and

retracting said one needle, such that at least said portion is carried along by said one needle with said attached thread.

11. A method according to claim 10, wherein said portion comprises a tip of said needle.

12. A method according to claim 10, wherein said portion comprises an entire extent of said needle which enters said bone.

13. A bone-boring device, comprising:

at least one curved needle when is operative to extend to bore a hole in a bone;

a base holding said needle and adapted for being placed against a bone

a handle coupled to the base; and

a needle retractor, which retracts said needle when a force on said handle in a particular direction is lower than a predetermined amount and prior to said base retreating from said bone.

14. A bone-boring device, comprising:

at least one curved needle when is operative to extend to bore a hole in a bone;

a base holding said needle and adapted for being placed against a bone

a handle coupled to the base; and

a needle advancer, which advances said needle only when a force on said handle in a particular direction is higher than a predetermined amount and after said force urges base against said bone.

For the applicant,

Fenster & Co. Patent Attorneys Ltd.
c:113/01063

ABSTRACT

A bone boring device, comprising:

a hinge;

a handle coupled to said hinge;

at least one curved needle having a tip and rotatably mounted on the hinge, wherein when said tip is placed against bone and said needle is rotated on said hinge, said needle is urged into said bone. Preferably, the at least one needle comprises at least two needles.

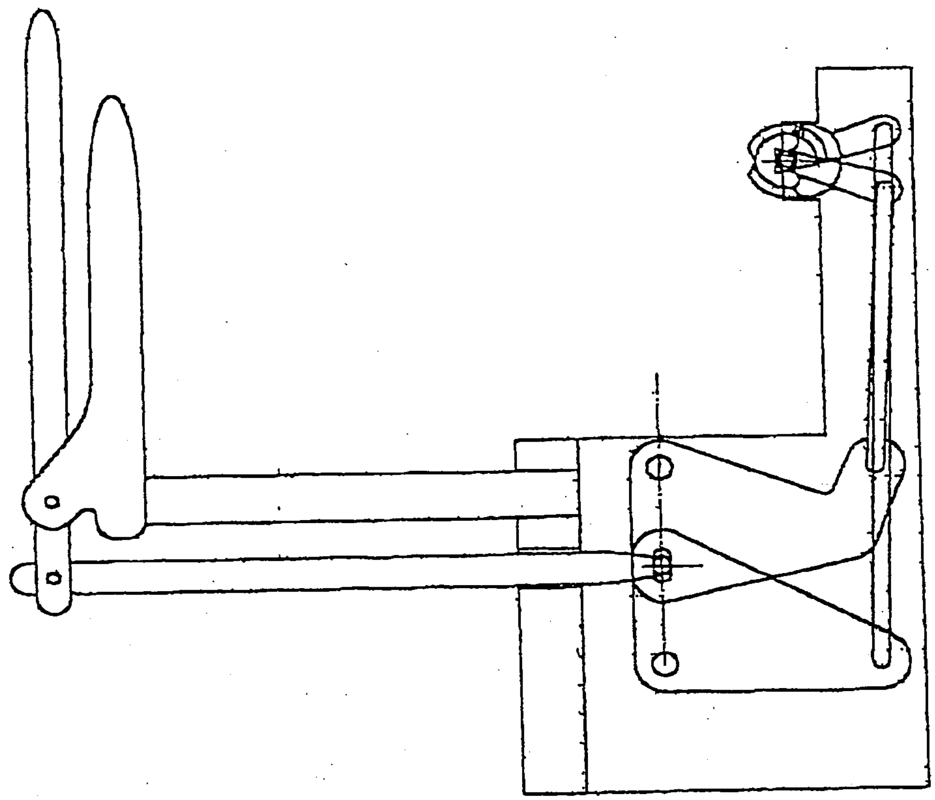


Fig. 1B

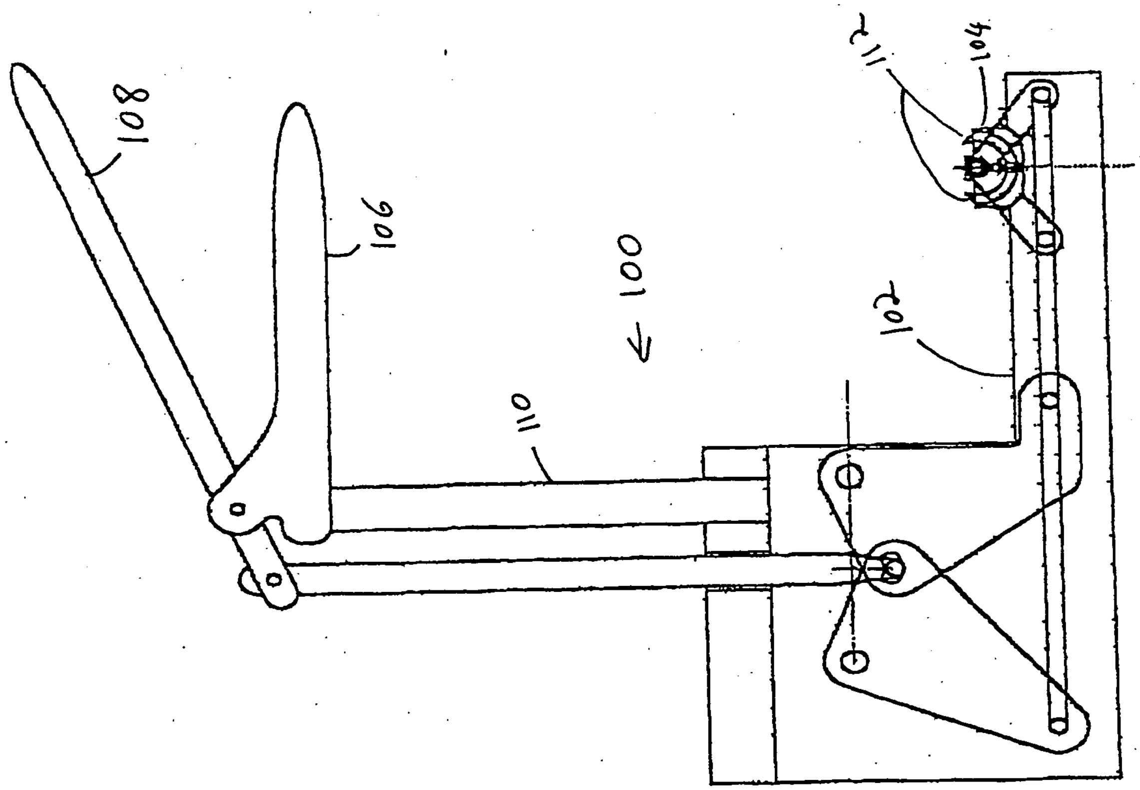


Fig. 1A

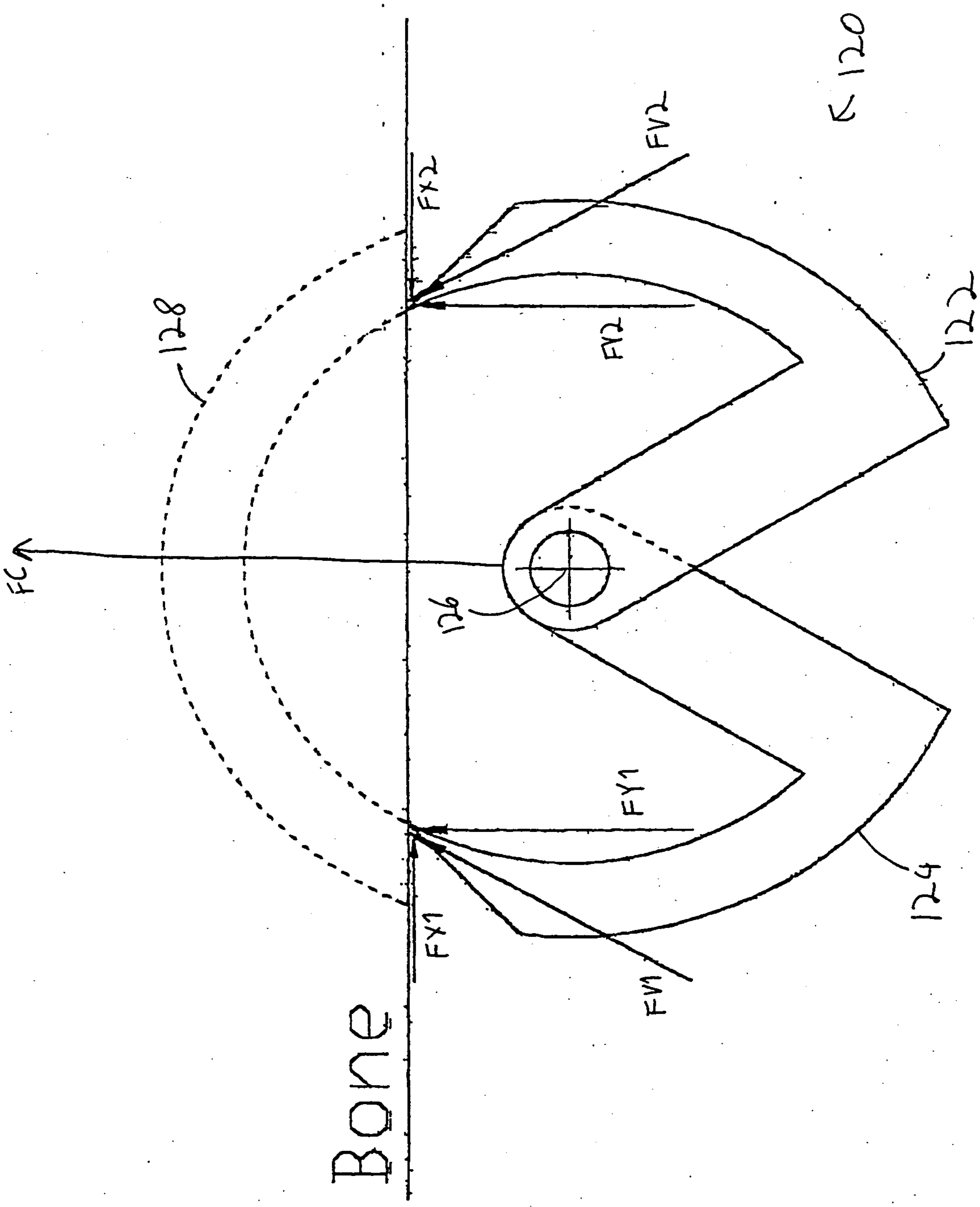


Fig. 2

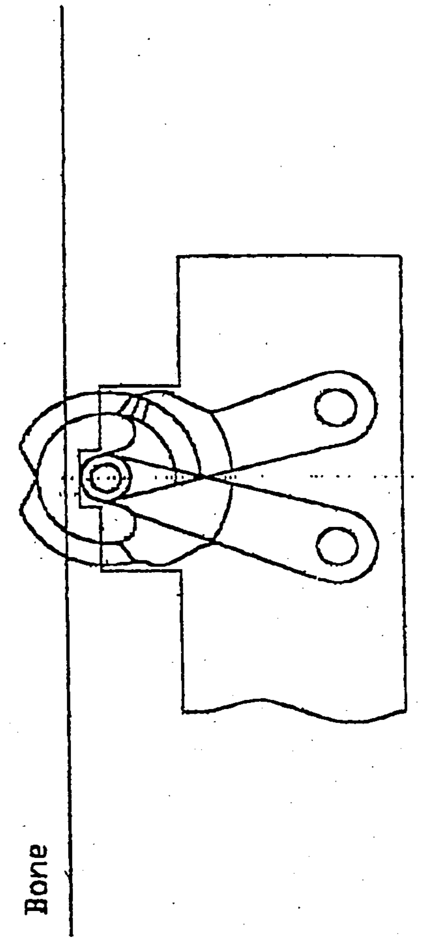


Fig. 3B

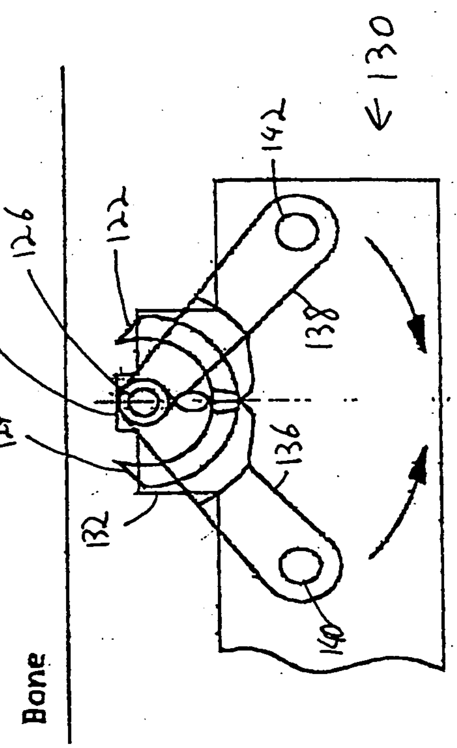


Fig. 3A

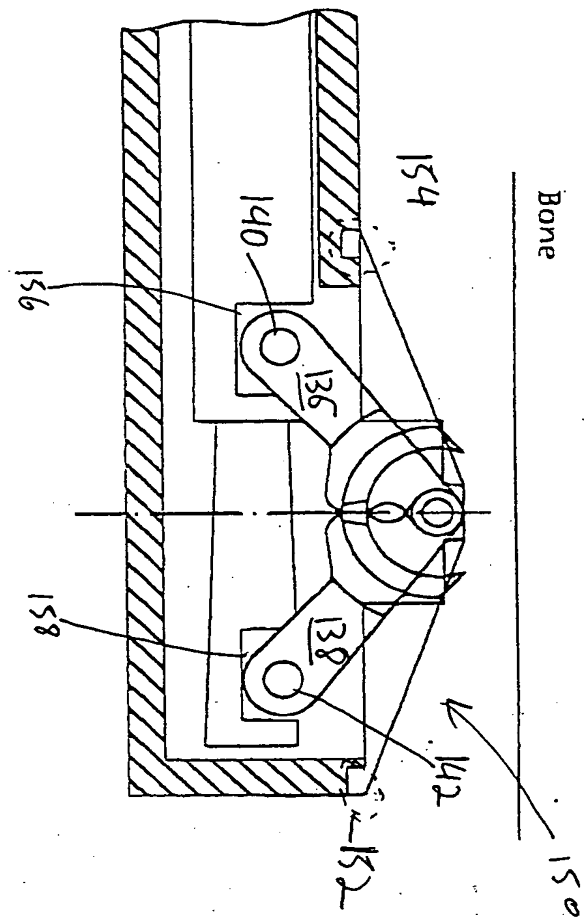
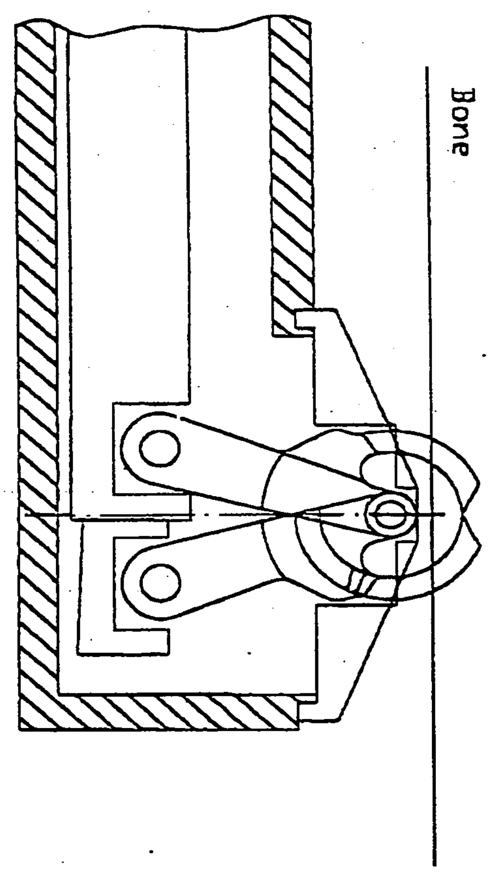


Fig. 3C



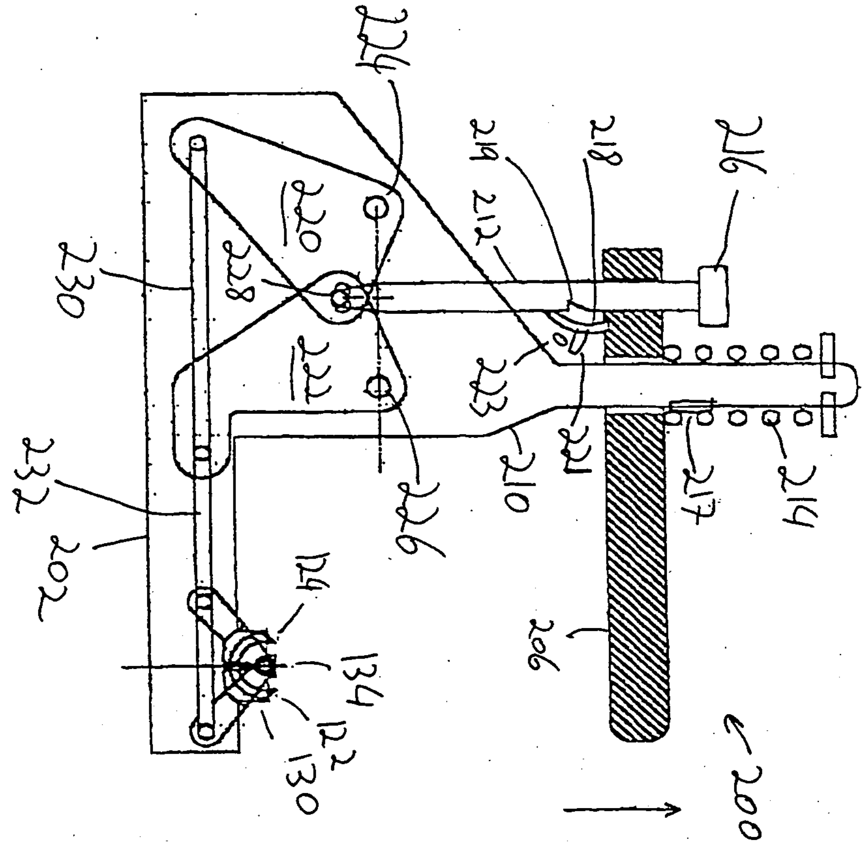

224
216
218
219
212
220
228
230
222
223
221
226
210
217
214
232
202
124
134
206
122
130
200

Fig 4A

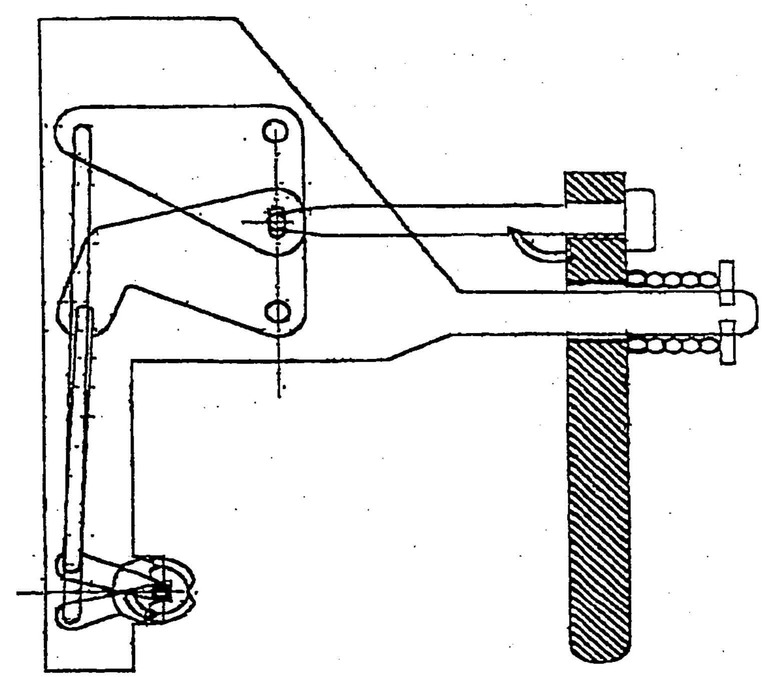


Fig 4B

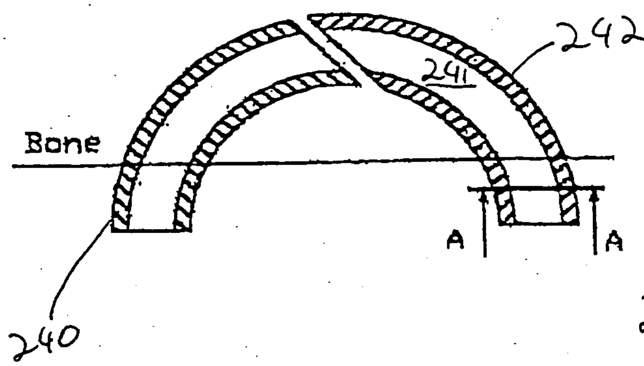


Fig 5A

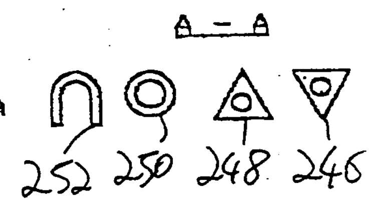


Fig 5B

Fig 6A

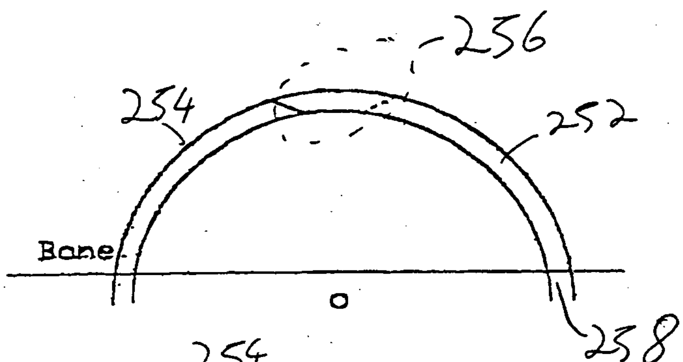
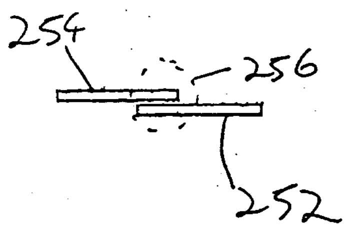


Fig 6B



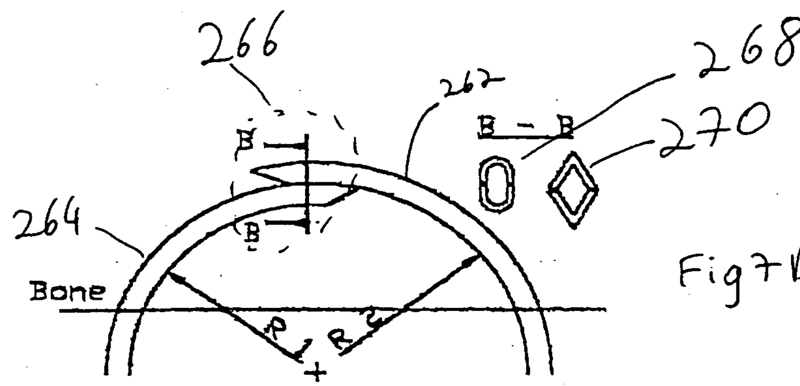


Fig 7B

Fig. 7A

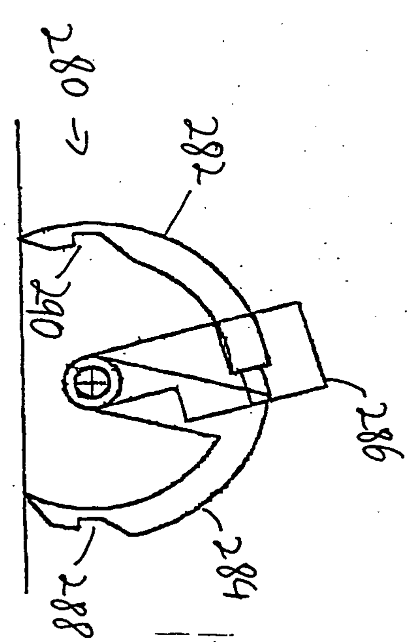


Fig 8A

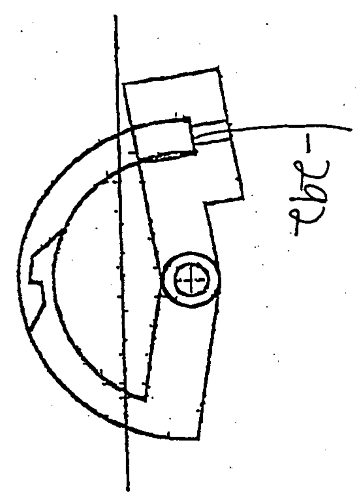


Fig. 8B

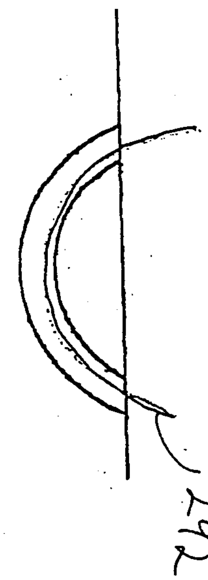


Fig 8C

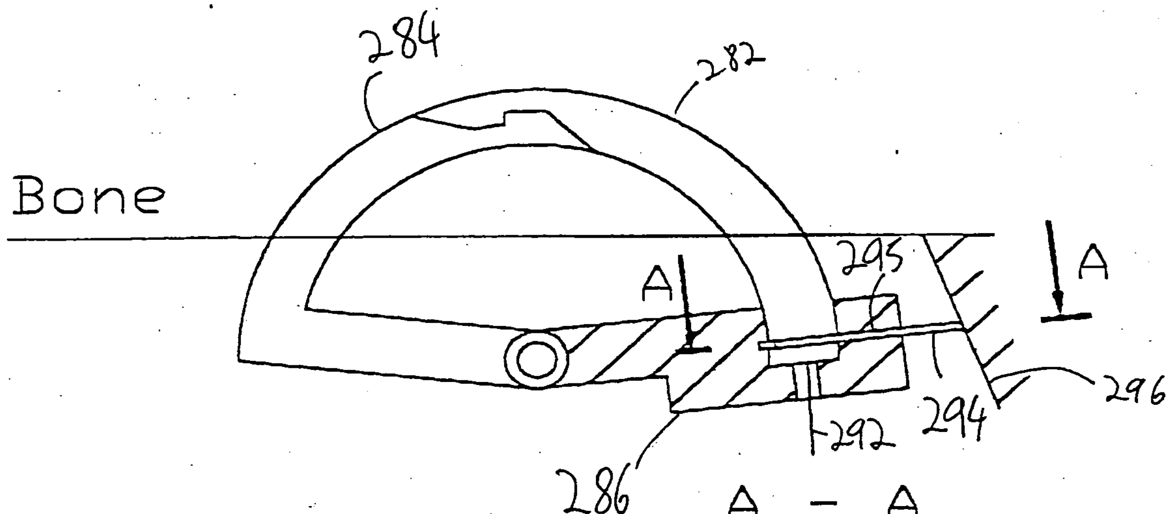


Fig 8D

A – A

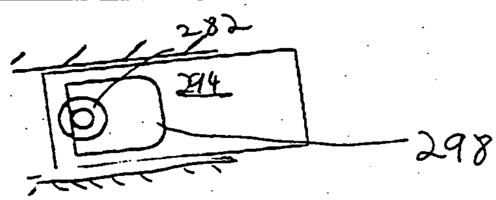


Fig. 8E

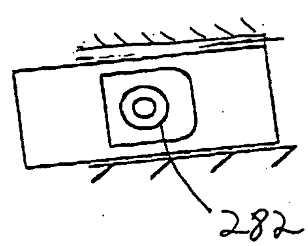
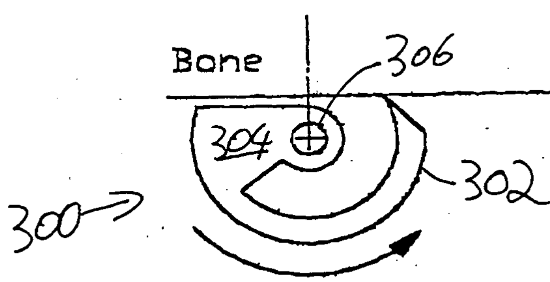


Fig. 8F



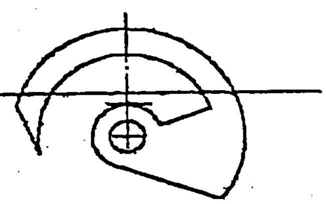


Fig. 9A

Fig. 9B

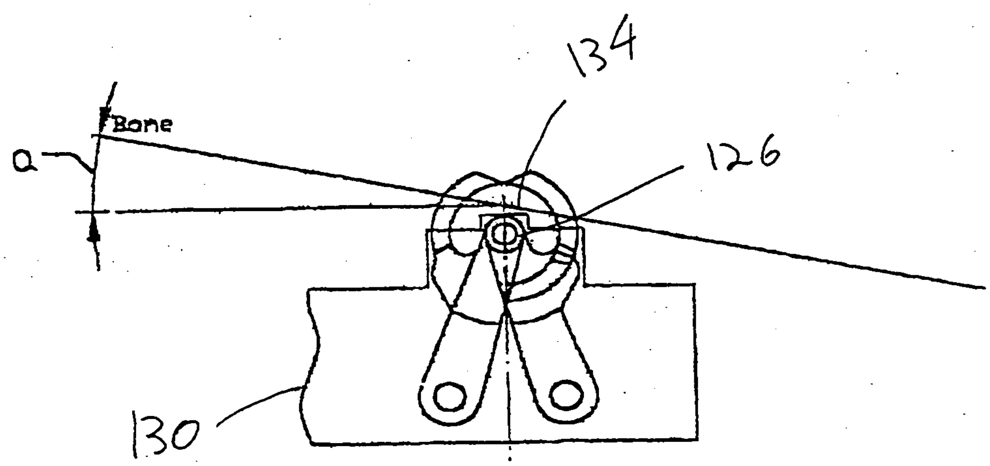


Fig. 10

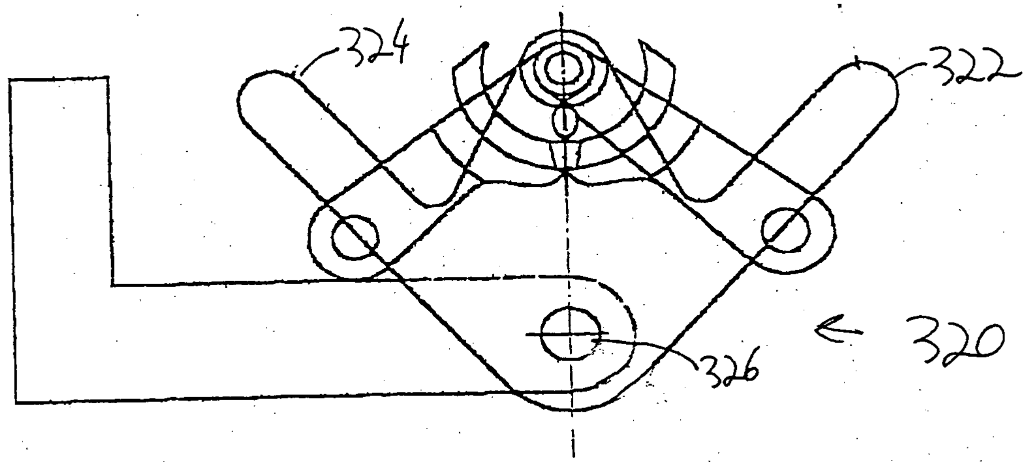


Fig. 11

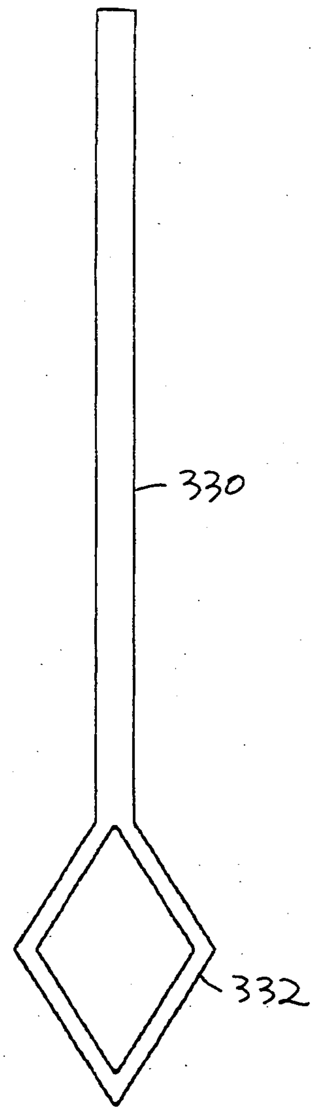


Fig. 12A

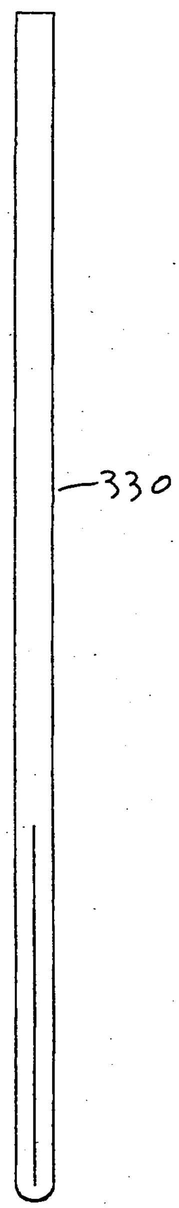


Fig. 12B

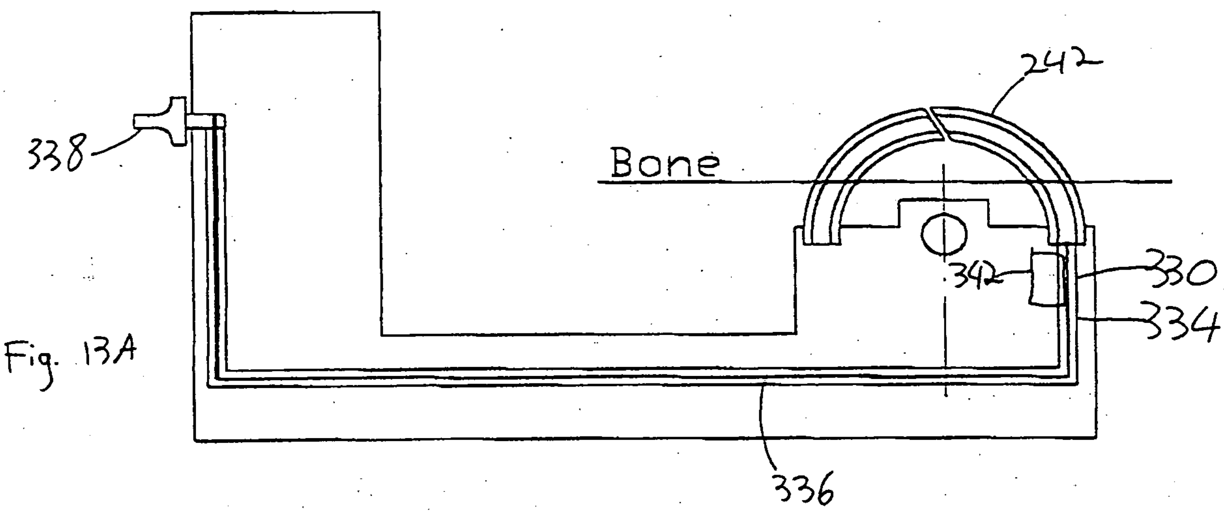


Fig. 13A

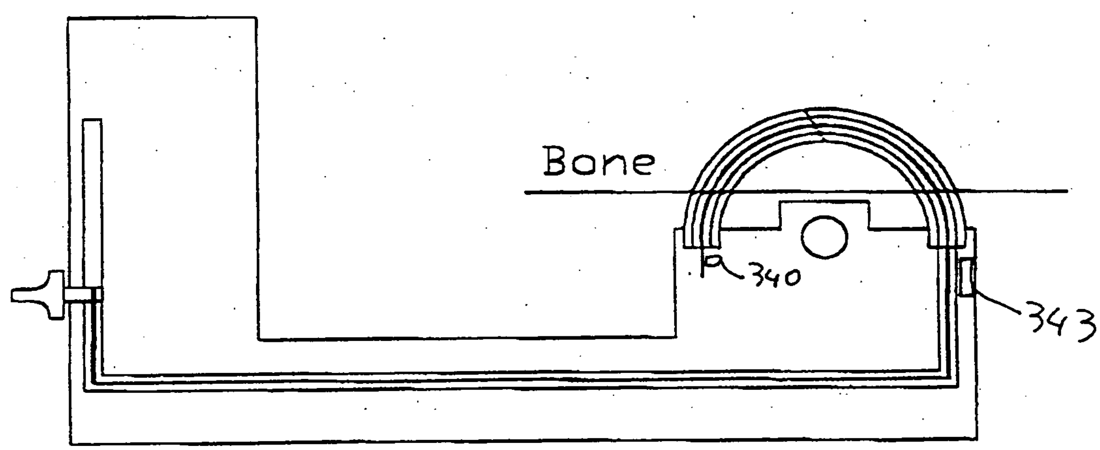


Fig 13B

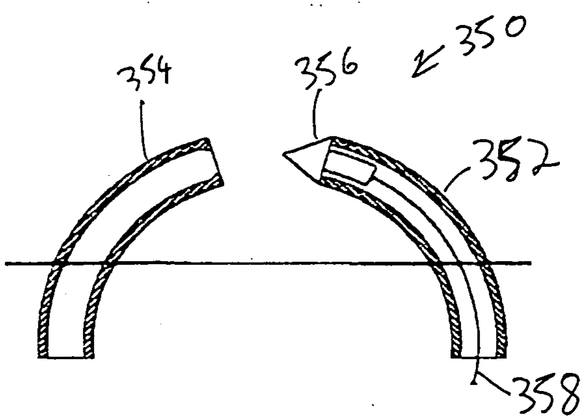


Fig. 14A

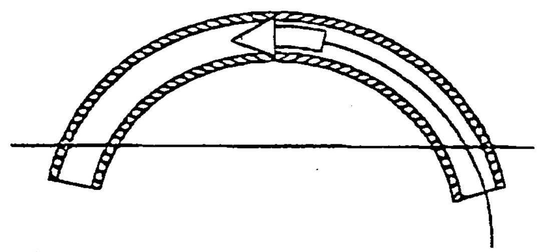


Fig. 14B

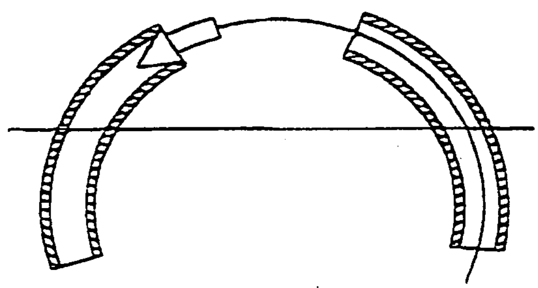


Fig. 14C

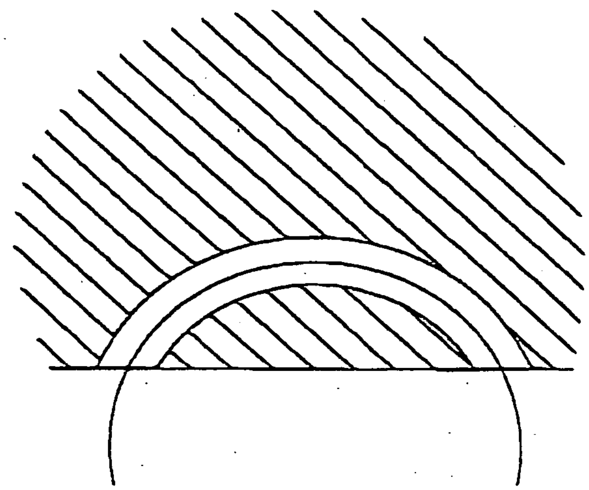


Fig 14D

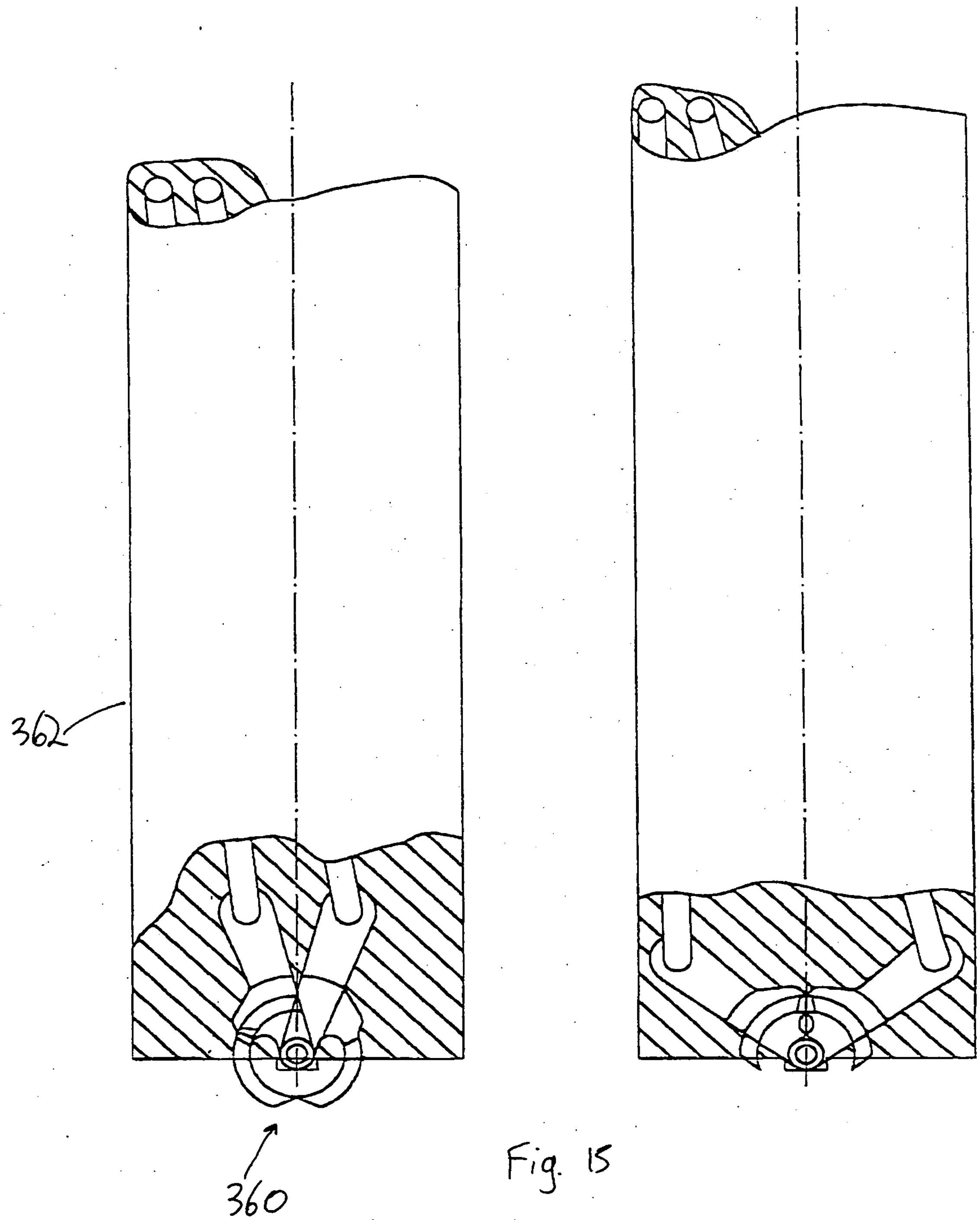


Fig. 15

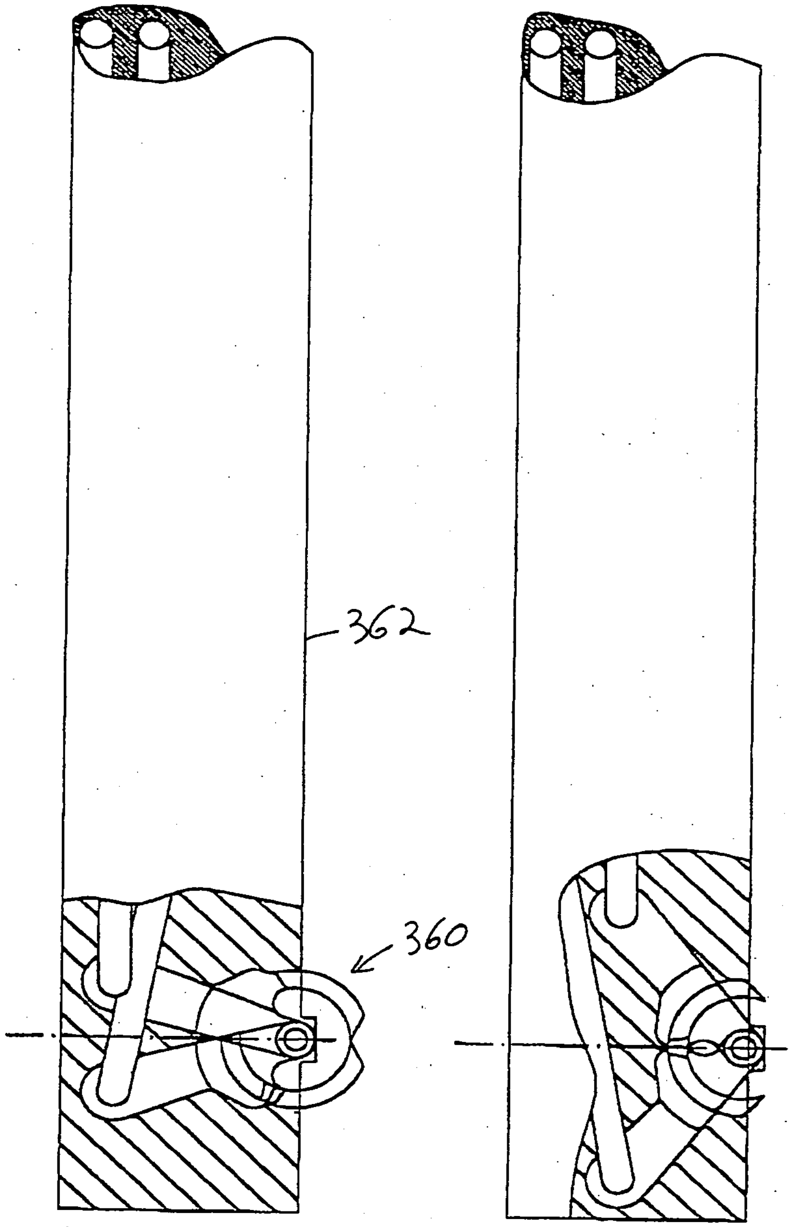


Fig. 16

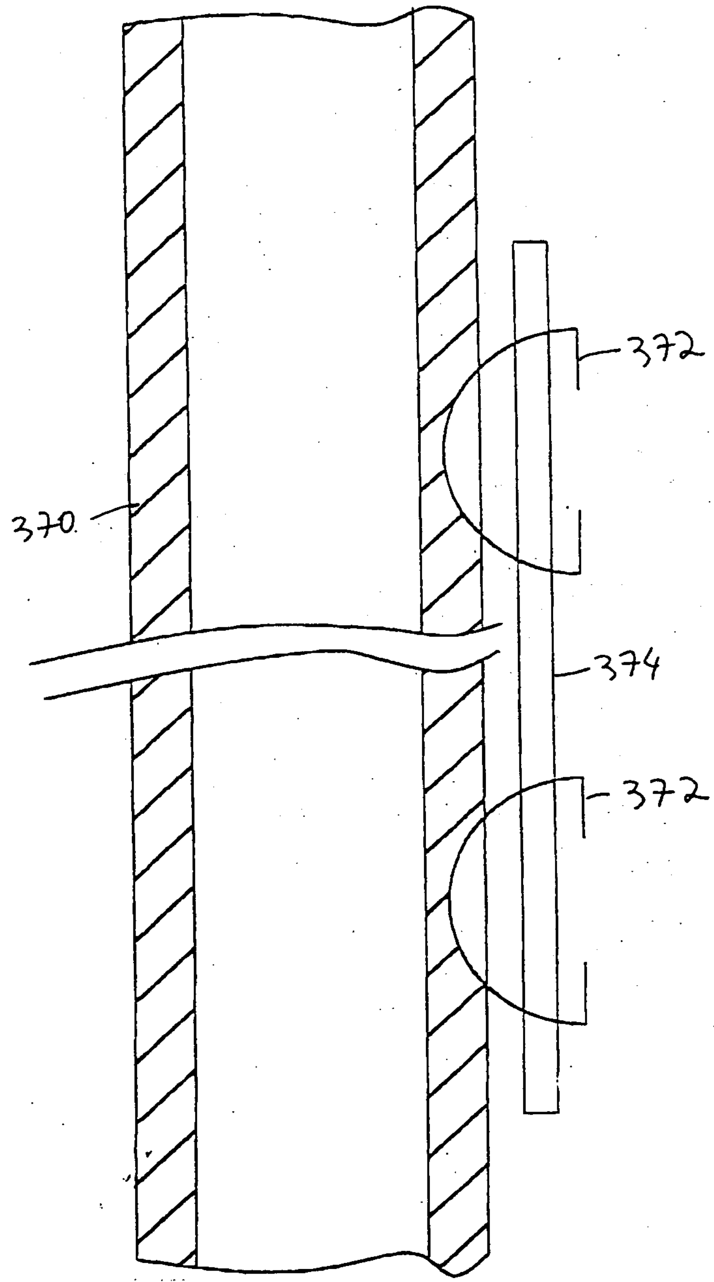


Fig 17